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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 779,427	02/08/2001	Alexander Stembuchel	11899.0152 DVUS01	5586

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/779,427

Examiner

Gerald Leffers, Jr.

Applicant(s)

STEINBUCHER ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2002.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of.
- 1 ☐ Certified copies of the priority documents have been received.
- 2 ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- 3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- 4 ☐ List of the certified copies not received.
- 5 ☐ 35 U.S.C. 119(e) (to a provisional application).

- a) ☐ The translation of the priority document is/are:
- 15) ☐ Acknowledgment is made of a claim for domestic priority.

- 4) ☐ Interview Summary: PTO-415, Patent No. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application: PTO-150

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## DETAILED ACTION

### *Election/Restrictions*

Applicants' election without traverse of Group I (claims 1-18) in Paper No. 6, filed 7/15/02, is acknowledged. Applicants' cancellation of the nonelected claims (claims 23-30) is also acknowledged. Claims 1-18 are pending in this application.

### *Information Disclosure Statement*

Receipt is acknowledged of an information disclosure statement, filed 2/8/01 as Paper No. 4. The signed and initialed PTO Form 1449 has been mailed along with this action.

### *Oath/Declaration*

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). **There are non-initial/non-dated changes to the address for Mathias Leibergesell.**

### *Specification*

The disclosure is objected to because of the following informalities: the plasmid pHP1014::156 appears to be mislabeled throughout the specification as "pHP1014::EIS6".

Appropriate correction is required

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*Claim Objections*

Claims 1-18 are objected to because of the following informalities: the claims lack an article "A" or "The" at the beginning of the claims. Appropriate correction is required.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The application and claims are directed towards combinations of specific bacterial strains and specific plasmids that are encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. The bacterial strains include: *Pseudomonas putida* GPp104 (pHP1014::E156), *Pseudomonas putida* GPp104 (pHP1014::B28+) (DSM #9417), *Alcaligenes eutrophus* PHB 4 (pHP1014::E156), and *Alcaligenes eutrophus* PHB 4 (pHP1014::B28+) (DSM #9418). Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809

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It is unclear whether this biological material is known and readily available to the public or that the teachings of the prior art and instant specification are sufficient to allow one of skill in the art to reliably reproduce the exact genetic backgrounds of the recited strains and/or the exact polynucleotide sequence of the recited plasmids. The prior art teaches that the strains *Pseudomonas putida* GPp104 and *Alcaligenes eutrophus* PHB 4 are known in the art. The prior art teaches that the base plasmid (pHP1014) used to construct the two plasmids of the invention (pHP1014::E156 and pHP1014::B28+) was known in the art. However, it is not clear that the base plasmid and the two strains are readily available to one of skill in the art that wishes to practice the claimed invention.

While it is clear from reading the specification that one of skill in the art could construct the claimed combinations of strains and plasmids if *Pseudomonas putida* GPp104, *Alcaligenes eutrophus* PHB 4 and pHP1014 are readily available to anyone of skill in the art, it is not apparent that one of skill in the art could reconstruct these exact strains and plasmids if the two strains and base plasmid are not readily available. For example, Huisman et al (J. Biol. Chem. 1991, Vol. 266, pages 2191-2198; see Table 1) discloses that the strain *P. putida* GPp104 is an NTG mutant of strain KT2442 that lacks PHA synthase activity. The prior art, however, does not appear to teach anywhere the exact genetic mutation responsible for generating the GPp104 PHA<sup>-</sup> strain (e.g. which codons are altered). Similarly, Pries et al teach the construction of pHP1014 from a previous plasmid, pVK101 (J. Bacteriology, 1991, Vol. 173, No. 18, pages 5843-5853; e.g. Construction of pHP1014 and pHP1016, page 5845). It is not clear, however, that the plasmid pVK101 or its predecessors are readily available to the public. Nor do the

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prior art. Given the apparent lack of specific teachings regarding the exact nature of the genetic background of at least one of the strains (i.e. *P. putida* GPp104), and the lack of teachings regarding the exact nucleotide make-up of the plasmid pHP1014, it would take undue experimentation for one of skill in the art to construct the recited combinations of specific strains and specific plasmids if *Pseudomonas putida* GPp104, *Alcaligenes eutrophus* PHB 4 and pHP1014 are not readily available to anyone of skill in the art.

Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. **In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment.** Because such deposit will not have been made prior to the effective filing date of the instant application, at least for the strains *Pseudomonas putida* GPp104 (pHP1014::E156) and *Alcaligenes eutrophus* PHB 4 (pHP1014::E156), applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of

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It appears that applicants may be in compliance with the rules for deposit of biological material for two of the recited combinations of bacterial strain/plasmid. At page 13, lines 2-11, of the instant specification there is an indication that strains *Pseudomonas putida* GPp104 (pHP1014::B28+) (DSM #9417) and *Alcaligenes eutrophus* PHB 4 (pHP1014::B28+) (DSM #9418) were deposited under the terms of the Budapest Treaty at an accepted depository. It is unclear, however, from reading this passage that applicants were the depositors, and in any case there remains no declaration that any possible restrictions on availability of the strains will be removed upon issuance of a patent on the claimed material. If applicants were in fact the party to make the deposition, then an affidavit or declaration by Applicant or a statement by an attorney of record over his or her signature and registration number, stating that the specific material has been deposited under the Budapest Treaty and that the material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein for the strains *Pseudomonas putida* GPp104 (pHP1014::B28+) (DSM #9417) and *Alcaligenes eutrophus* PHB 4 (pHP1014::B28+) (DSM #9418).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

Claim 1 is vague and indefinite in that the plasmid in the strain "Alcaligenes eutrophus PHB 4 (pHP1014::EIS6)" appears to be mislabeled in view of the specification. This makes it unclear what exactly is claimed. Although the phrase "pHP1014::EIS6" does appear in the specification, the specification teaches that it is a 15.6 kb EcoR I fragment that was used to generate the plasmid pHP1014::E156 (e.g. page 23, lines 16-23; Example 2). It would be remedial to amend the claim to read strain "Alcaligenes eutrophus PHB 4 (pHP1014::E156)".

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "...carbon source selected from the group consisting of: levulinic acid, salts of levulinic acid, esters of levulinic acid, lactones of levulinic acid, substituted levulinic acid or, as the case may be, its derivatives; 5-hydroxyhexanoic acid, its salts, esters and lactones; 4-hydroxyheptanoic acid, its salts, esters and lactones; 4-hydroxyoctanoic acid, its salts, esters and lactones; their halogenated derivatives, as well as their mixtures..." are unclear on multiple grounds as follows. In general, it would be remedial to amend the claim language to clearly spell out each compound in proper Markush group language to avoid confusion as to what compounds are actually claimed (e.g. "group consisting of levulinic acid, salts of levulinic acid, esters of levulinic acid, ..., 5-hydroxyhexanoic acid, salts of 5-hydroxyhexanoic acid, ..., 4-hydroxyoctanoic acid, salts of 4-hydroxyoctanoic acid, ... and combinations thereof".

- For example, the intended limitation of "as the case may be" is inherently unclear. It would be remedial to simply delete this language from the claim.
- The term "its derivatives" is also inherently indefinite on different levels. First



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already been listed that would reasonably be considered derivatives of the original compound. Secondly, the antecedent basis for the term "its" is not clear as the claim is written, making it unclear what is referred to by the term (e.g. does "its" refer to levulinic acid or substituted levulinic acid, or both?). Thirdly, the term "derivative" is not clearly defined in the instant specification. Just how different can a compound be from levulinic acid, for example, and still be considered a "derivative"?

- Likewise, the metes and bounds of the words "their halogenated derivatives" are unclear. Again, how different can a compound be from levulinic acid, for example, and still be considered a "derivative"? Also, there is no clear and positive prior antecedent basis for the cited phrase. Does the phrase refer to just 4-hydroxyoctanoic acid, or does it refer to each compound listed?
- Finally, does the term "their mixtures" refer to each of the compounds listed in the Markush group? Also, does the term encompass a "mixture" comprising only one of the compounds listed in the group, or does it refer to different combinations of the different members of the group? It would be remedial to amend the claim to clearly indicate which members of the Markush group of carbon sources is referred to by the limitation and whether the limitation is directed to any mixture comprising a single member or to different *combinations* of the different members.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "a certain

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limitation of "a certain time"? It would be remedial to amend the claim language to indicate a clear time that the bacterial culture is to be incubated in order to practice the claimed method.

Claim 3 is vague and indefinite in that the metes and bounds of the phrase "...carbon source is selected from the group comprising: citric acid, octanoic acid and gluconic acid; their salts, esters and lactones; hexoses, especially glucose and fructose; as well as their mixtures..." are unclear. First, the use of "a group comprising:" leaves open the question as to what other compounds might be comprised within the group and not listed. It would be remedial to amend the claim language to "a group consisting of". Secondly, the phrase "...hexoses, especially glucose and fructose..." is inherently indefinite because it cites two members of a larger group in the same claim as the larger group (i.e. hexoses). It would be remedial to drop this phrase from the claim. Finally, as indicated above, the term "mixtures" is indefinite because it makes it unclear if the term embraces just one of the compounds in some sort of mixture (e.g. in water) or whether it is meant to embrace different combinations of the recited compounds. If the latter is accurate, it would be remedial to amend the claim to something like "and combinations thereof".

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

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the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation "approximately 15 to 70% by weight", and the claim also recites "approximately 15 to 50% by weight" and "approximately 40% by weight" which are the narrower statements of the range/limitation. It would be remedial to amend the claims by separating each of the ranges into different claims.

Claim 5 is also vague and indefinite in that the terms "especially" and "preferably" add no definite limitation to the claim and make it unclear as to whether the recited limitations for concentration of poly(hydroxy fatty acid) are actually claimed in the alternative, as they should be. It would be remedial to delete these terms from the claim language.

Claim 6 is vague and indefinite in that the metes and bounds of the term "preferably" are unclear. The term adds no definite limitation to the claim and makes it unclear as to whether the recited limitations for the number of subunits are actually claimed in the alternative, as they should be. It would be remedial to simply delete "preferably" from the claim language.

Claims 7, 12 and 13 recite the terms "cultivated" or "cultivation". These terms are indefinite in that it is unclear whether they refer to the incubation step of claim 1, upon which each of these claims are dependent, or whether they refer to some other step for which there is no clear antecedent basis. If these terms do in fact refer to the incubation step of claim 1, it would be remedial to substitute for these terms language that is consistent with the term "incubates" in claim 1 (e.g. "incubation" or "incubated").

Claim 9 is vague and indefinite in that the metes and bounds of the word "uses" are

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"offered" to the bacteria at the beginning of the method of claim 1, or that the recited concentration is maintained throughout the incubation step of claim 1? It would be remedial to amend the claim language to clearly indicate how the carbon source is "used".

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 11 recites the broad recitation "approximately 27°C to 35°C", and the claim also recites "approximately 30°C" which is the narrower statement of the range/limitation. It would be remedial to recite the limitation of "approximately 30°C" in a dependent claim.

Claim 11 is also vague and indefinite in that the metes and bounds of the phrases "in each case" and "preferably" are unclear. There is no clear and positive prior antecedent basis for the term "in each case". It appears the word case may refer to the "steps" of adding substrate carbon source that are recited in claim 10, upon which claim 11 is dependent. If this is so, it would be

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remedial to amend the claim language to make it clear that the limitations recited in claim 11 refer to the stepwise addition of substrate carbon source referred to in claim 1).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 12 recites the broad recitation "24 h to 96 h", and the claim also recites "36 h to 72 h" and "48 h to 72 h" which are the narrower statements of the range/limitation. It would be remedial to place each range within a separate claim.

Claim 12 is also vague and indefinite in that the terms "especially" and "preferably" add no definite limitation to the claim and make it unclear as to whether the recited limitations for cultivation period are actually claimed in the alternative, as they should be. It would be remedial to delete these terms from the claim language.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim

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explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 13 recites the broad recitation "deficiency", and the claim also recites "preferably deficiency of nitrogen, magnesium or phosphate" which is the narrower statement of the range/limitation. Also, as indicated above, the term "preferably" is inherently indefinite. It is further unclear if the deficiency is only limited to the recited types of "deficiency", or includes other, non-disclosed types of deficiency. If the latter is true, then the metes and bounds of the claim are further indefinite in that there is no means of determining what type of deficiency is encompassed by the term "deficiency". It would be remedial to amend the claim language to include a Markush group consisting of the recited types of deficiency.

Claim 14 is vague and indefinite in that the metes and bounds of the phrase "...physical and/or chemical and/or biochemical processes..." are unclear. The phrase is unclear in that the multiple uses of the term "and/or" makes unclear the exact combinations of processes that are permissible. The claim language would be less indefinite if amended to something like "...by means of physical, chemical or biochemical processes, or combinations thereof...".

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A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 15 recites the broad recitation "an organic solvent", and the claim also recites "preferably chloroform or methylene chloride" which is the narrower statement of the range/limitation. Also, as indicated above, the term "preferably" is indefinite.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

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the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 16 recites the broad recitation "a hydrophilic solvent", and the claim also recites "...especially water or a lower alcohol, preferably ethanol..." which is the narrower statement of the range/limitation. As noted above, the terms like "preferably" and "especially" are inherently indefinite and should be deleted from the claim language.

Claim 18 is vague and indefinite in that the phrase "selected from the group which comprises" implies that there are potentially other, undisclosed, members of the group that cannot be determined. It would be remedial to amend the claim language to "selected from the group consisting of". Claim 18 is also vague and indefinite in that it is unclear whether the term "mixtures" embraces any mixture comprising only a single member of the Markush group or whether the term is meant to embrace different *combinations* of the Markush group members. It would be remedial to amend the claim language to clearly indicate which interpretation of the term "mixtures" is correct.

### *Conclusion*

No claims are allowed. The prior art does not anticipate, or reasonably suggest, the combinations of bacterial strains/plasmid and substrate carbon sources recited in the instant claims. Therefore, the instant claims are free of the art.

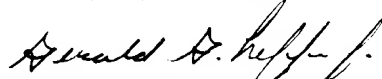


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Gerald G Leffers Jr.  
Examiner  
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ggl  
August 26, 2002

# SUBMISSION FOR DEPOSIT OF BIOLOGICAL MATERIAL

ATTACHMENT

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.803(a)(2)).
5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.803(a)(1)).
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.803).
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 441 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be identified in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.